

FIG. 1

FIG. 2 is a block diagram of a system 100 for managing biomedical data. The system 100 includes a web portal 108, a discovery data collection GUI 104, a clinical studies data collection GUI 104, an FDA approval GUI 104, and a product release data collection GUI 104. The system 100 also includes a biomedical data warehouse 44, which contains a discovery metadata structure 106, a clinical studies metadata structure 106, an FDA approval metadata structure 106, and a product release metadata structure 106. The system 100 further includes a first entity, a second entity, and an Nth entity, which are connected to the web portal 108.

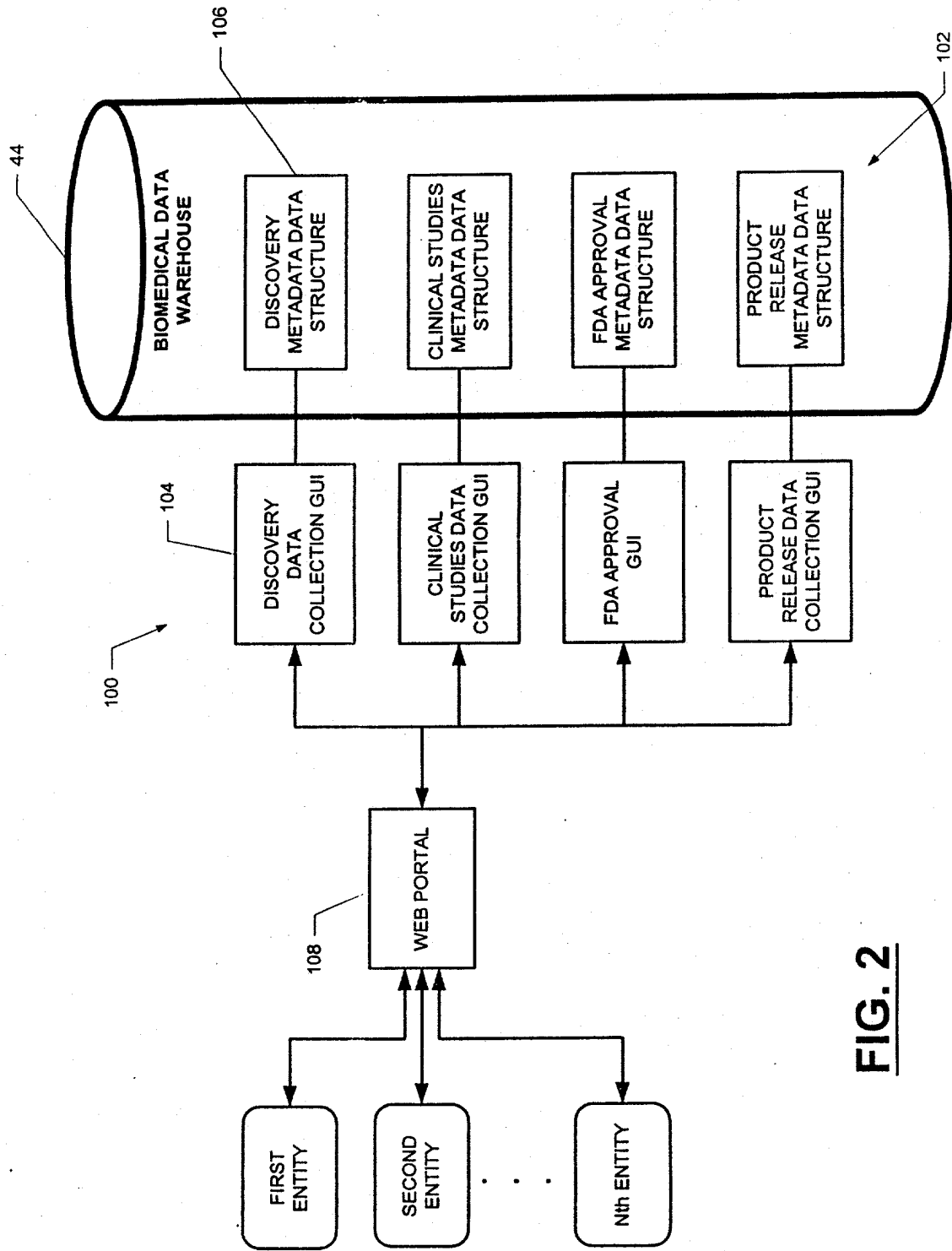


FIG. 2

| | | |
|---------------------------------------|---|-----------------------------|
| Administration route: Formulation: | <div> <div>intravenous drip</div> <div>aqueous</div> </div> | Other: <input type="text"/> |
| Date Expiry or enabled?: R | | 150 |
| Patient column: | | 152 |
| Visit column: | | 154 |
| Study period column: | | |
| Number of periods: | 3 | |
| Baseline value of visit: | 0 | |
| Trails and Footnotes: | Edit | |

FIG. 3

| Columns | | Name | Label | Display name | Type | Length | Format | edit | delete | add new |
|--------------------------|---------|---------------------------------|-------|--------------|-----------|--------|--------|------|--------|---------|
| <input type="checkbox"/> | age | Age in Years at Baseline | | | Numeric | 8 | BES112 | | | |
| <input type="checkbox"/> | medsdy | Actual Day of Visit/ConductExam | | | Numeric | 8 | BES112 | | | |
| <input type="checkbox"/> | HEIGHT | Height in Centimeters | | | Numeric | 8 | BES112 | | | |
| <input type="checkbox"/> | Invname | Investigator Name | | | Character | 4 | %4 | | | |
| <input type="checkbox"/> | race | Race | | | Character | 8 | %8 | | | |
| <input type="checkbox"/> | sex | Sex | | | Character | 8 | %8 | | | |
| <input type="checkbox"/> | studyid | Study ID | | | Character | 8 | %8 | | | |
| <input type="checkbox"/> | subjid | Subject ID | | | Numeric | 8 | BES112 | | | |
| <input type="checkbox"/> | trtid | Treatment Code | | | Numeric | 8 | BES112 | | | |
| <input type="checkbox"/> | TRTgrp | Treatment Group | | | Character | 8 | %8 | | | |
| <input type="checkbox"/> | WEIGHT | Weight in Kilograms | | | Numeric | 8 | BES112 | | | |

[NONE] [NONE] [NONE]

edit delete

FIG. 4

190
192

Load uploaded from path: G:\VMDAT\Nicaah2\shonk\adverse.aad7\dat

| Column | Name | Label/Description | Type | Length | Format | Inform |
|----------------------------------|-----------------------------|-------------------|-----------|--------|--------|--------|
| <input type="checkbox"/> secm | Comment | | Numeric | 8 | BEST12 | F12 |
| <input type="checkbox"/> ecdecod | AE Decode from Dictionary | | Character | 21 | \$F21 | \$F21 |
| <input type="checkbox"/> ecout | Outcome of Event | | Numeric | 8 | BEST12 | F12 |
| <input type="checkbox"/> eesev | Severity/Intensity of Event | | Numeric | 8 | BEST12 | F12 |
| <input type="checkbox"/> studyid | Study ID | | Character | 8 | \$F8 | \$F8 |
| <input type="checkbox"/> subid | Subject ID | | Numeric | 8 | BEST12 | F12 |

Default measure definition column:
Default measure definition column type:
Default measure grouping column:

Keys

| Key name | Description | Key order | Key sort order |
|----------------------------------|-------------|-----------|----------------|
| <input type="checkbox"/> studyid | Study ID | 1 | Ascending |
| <input type="checkbox"/> subid | Subject ID | 2 | Ascending |

Unique by Keys?: ☐

FIG. 5

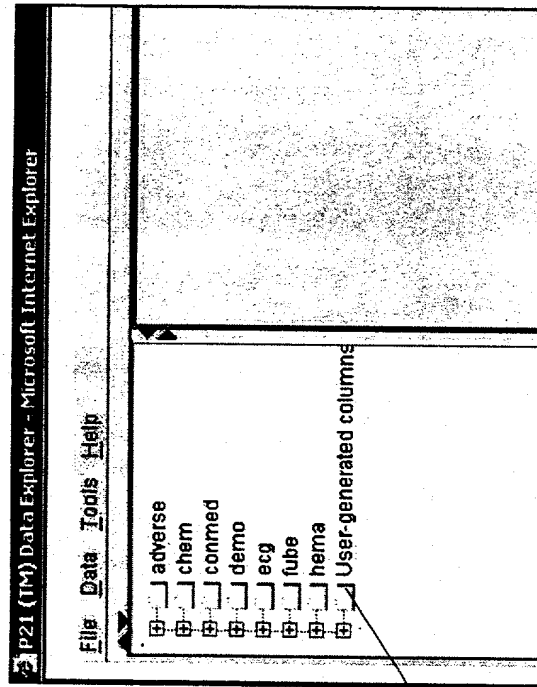


FIG. 6

Microsoft Internet Explorer 4.0 (64-bit)
Address: http://www.microsoft.com/...
File Edit View Favorites Tools Help

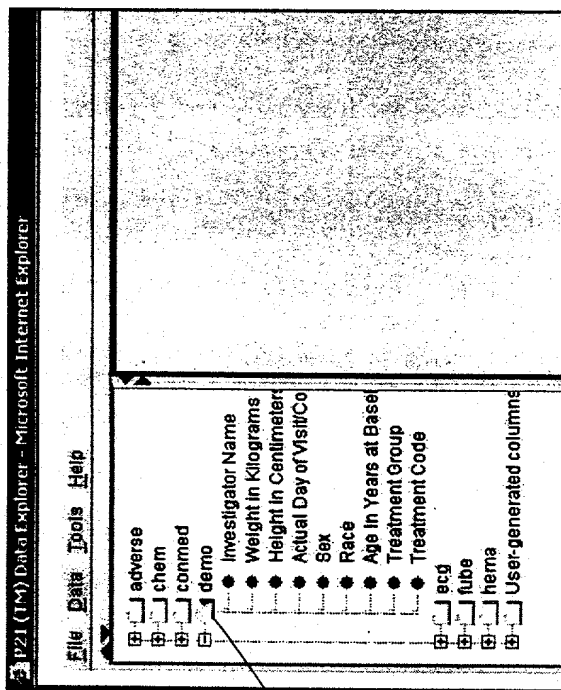
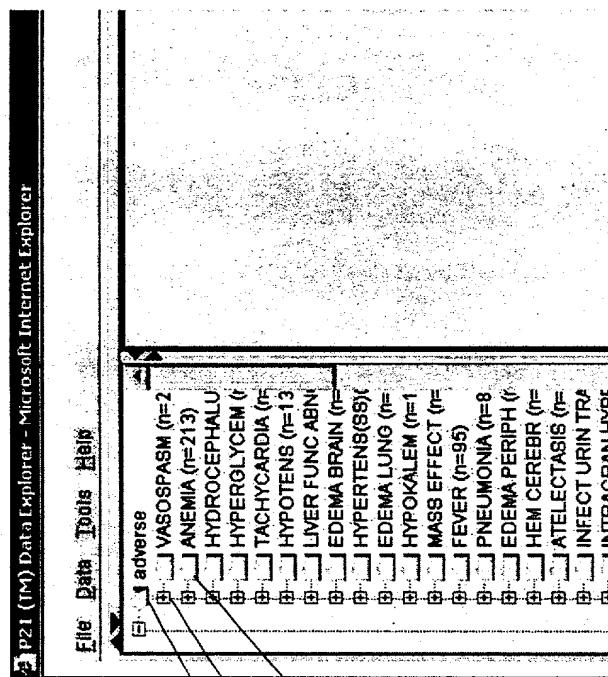


FIG. 7



220

222

224

200

FIG. 8

FIG. 9 is a screenshot of a Microsoft Internet Explorer window displaying a data table. The window title is "p21 (TM) Data Explorer - Microsoft Internet Explorer". The table has columns for Patient ID, Sex, Race, and Investigator. The data is organized into rows, with some rows having a "User-generated column" at the end. The table is displayed in a standard web browser interface with a menu bar (File, Data, Tools, Help) and a status bar.

238 240 236

230

232 234 200

| | Patient ID | Sex | Race | Investigato... |
|----|-----------------|--------|-----------|----------------|
| 1 | NICSAH2 :112... | Male | Caucasian | 011A |
| 2 | NICSAH2 :112... | Male | Black | 011A |
| 3 | NICSAH2 :112... | Female | Caucasian | 011A |
| 4 | NICSAH2 :112... | Male | Other | 011A |
| 5 | NICSAH2 :112... | Female | Caucasian | 011A |
| 6 | NICSAH2 :112... | Female | Caucasian | 011A |
| 7 | NICSAH2 :112... | Female | Caucasian | 011A |
| 8 | NICSAH2 :112... | Male | Caucasian | 011A |
| 9 | NICSAH2 :112... | Male | Caucasian | 011A |
| 10 | NICSAH2 :112... | Male | Caucasian | 011A |
| 11 | NICSAH2 :112... | Female | Caucasian | 011A |
| 12 | NICSAH2 :112... | Female | Caucasian | 011A |
| 13 | NICSAH2 :112... | Male | Caucasian | 011A |
| 14 | NICSAH2 :112... | Female | Black | 011A |
| 15 | NICSAH2 :112... | Male | Caucasian | 011A |
| 16 | NICSAH2 :112... | Male | Caucasian | 011A |
| 17 | NICSAH2 :112... | Female | Black | 011A |

adverse
chem
conmed
demo
Investigator Name
Weight in Kilograms
Height in Centimeter
Actual Day of Visit/Co
Sex
Race
Age in Years at Baseline
Treatment Group
Treatment Code
ecg
tube
hema
User-generated column

FIG. 9

FILE EDIT VIEW DATA TOOLS HELP
Date: 11/10/2001 11:11:11 AM
Page: 1 of 1
Data: 11/10/2001 11:11:11 AM

252

File Edit View Data Tools Help

121 (1st) Data Explorer - Microsoft Internet Explorer

1 adverse

1 VASOSPASM (n=2)

1 ANEMIA (n=213)

1 HYDROCEPHALUS

1 HYPERGLYCEM (n=)

1 TACHYCARDIA (n=)

1 HYPOTENS (n=13)

1 # Reports

1 Severity/Intensit

1 N

1 Minimum

1 Maximum

1 Mean

1 Outcome of Eys

1 N

1 Minimum

1 Maximum

1 Mean

1 Comment

1 LIVER FUNC ABNC

1 EDEMA BRAIN (n=)

1 HYPERTENS(S/S)

1 EDEMA LUNG (n=1)

1 HYPOKALEM (n=1)

1 MASS EFFECT (n=)

1 FEVER (n=95)

| # | Patient ID | Sex | Race | HYPOTENS Reported |
|----|-------------|--------|-----------|-------------------|
| 1 | NICSAH2-112 | Male | Caucasian | Y |
| 2 | NICSAH2-112 | Male | Black | Y |
| 3 | NICSAH2-112 | Female | Caucasian | Y |
| 4 | NICSAH2-112 | Male | Other | Y |
| 5 | NICSAH2-112 | Female | Caucasian | Y |
| 6 | NICSAH2-112 | Female | Caucasian | N |
| 7 | NICSAH2-112 | Female | Caucasian | N |
| 8 | NICSAH2-112 | Male | Caucasian | Y |
| 9 | NICSAH2-112 | Male | Caucasian | N |
| 10 | NICSAH2-112 | Male | Caucasian | N |
| 11 | NICSAH2-112 | Female | Caucasian | Y |
| 12 | NICSAH2-112 | Female | Caucasian | N |
| 13 | NICSAH2-112 | Male | Caucasian | Y |
| 14 | NICSAH2-112 | Female | Black | Y |
| 15 | NICSAH2-112 | Male | Caucasian | N |
| 16 | NICSAH2-112 | Male | Caucasian | Y |
| 17 | NICSAH2-112 | Female | Black | N |
| 18 | NICSAH2-112 | Male | Caucasian | N |
| 19 | NICSAH2-112 | Female | Caucasian | N |
| 20 | NICSAH2-112 | Female | Caucasian | N |
| 21 | NICSAH2-112 | Male | Caucasian | Y |
| 22 | NICSAH2-112 | Female | Caucasian | N |
| 23 | NICSAH2-112 | Female | Caucasian | N |
| 24 | NICSAH2-112 | Male | Caucasian | Y |
| 25 | NICSAH2-112 | Male | Caucasian | N |
| 26 | NICSAH2-112 | Female | Black | N |

250

200

FIG. 10

1. Select the variable to be analyzed.
 2. Select the variable to be analyzed.
 3. Select the variable to be analyzed.
 4. Select the variable to be analyzed.
 5. Select the variable to be analyzed.
 6. Select the variable to be analyzed.
 7. Select the variable to be analyzed.
 8. Select the variable to be analyzed.
 9. Select the variable to be analyzed.
 10. Select the variable to be analyzed.

260

Report

Basic Summary

prev

next

cancel

Population Data Set:

Home/N/A/and/line/MSAR Study/01

41

Select...

Clear

Grouping Variable:

Treatment Code [trcd]

Age in Years at Baseline [age]

Actual Day of Visit/Collection/Exam [dmactdy]

Height in Centimeters [HEIGHT]

Investigator Name [invname]

Race [race]

Sex [sex]

Study ID [studyid]

Subject ID [subjid]

Treatment Group [TRTGRP]

Weight in Kilograms [WEIGHT]

Summary Statistics:

| | |
|--------|--|
| n | |
| Mean | |
| Min | |
| Max | |
| StdErr | |
| Median | |
| StdDev | |

FIG. 11

Report

Basic Summary

prev / next / cancel

Population Data Set

1

Enter N/A or blank cell; S=H Study ID

Select...

Clear

Grouping Variable:

Treatment Code [trcat]

(see Treatment)

Variable:

Race [race]

Sex [sex]

Age in Years at Baseline [age]

Actual Day of Visit/Collection/Exam (dmocdyr)

Height in Centimeters [HEIGHT]

Investigator Name [invname]

Race [race]

Sex [sex]

Study ID [studyid]

Subject ID [subjid]

Treatment Code [trcat]

Treatment Group [TRTGRP]

Analysis Type:

DISCRETE

DISCRETE

Summary Statistics:

| | |
|-------|--------|
| N | Mean |
| Min | Max |
| StDev | Median |
| StDev | StDev |

270

FIG. 12

280

282

284

| Summary Variables | Treatment Code | | |
|---------------------|----------------|--------------|------------------|
| | 1 (N=181) | 2 (N=184) | Total (N=365) |
| Race | | | |
| Black | 41 (22.7) | 36 (19.6) | 77 (21.1) |
| Caucasian | 130 (71.3) | 138 (75.0) | 268 (73.4) |
| Oriental | 2 (1.1) | 4 (2.2) | 6 (1.6) |
| Other | 8 (4.4) | 6 (3.3) | 14 (3.8) |
| Sex | | | |
| Female | 134 (74.0) | 112 (60.9) | 246 (67.4) |
| Male | 47 (26.0) | 72 (39.1) | 119 (32.6) |
| Weight in Kilograms | | | |
| n | 181 | 184 | 365 |
| Mean | 69.4 | 73.4 | 71.5 |
| Median | 67.0 | 70.0 | 69.0 |
| Std. Dev | 15.80 | 16.71 | 16.37 |
| Std. Error | 1.17 | 1.23 | 0.86 |
| Minimum | 38 | 42 | 38 |
| Maximum | 149 | 134 | 149 |

FIG. 13

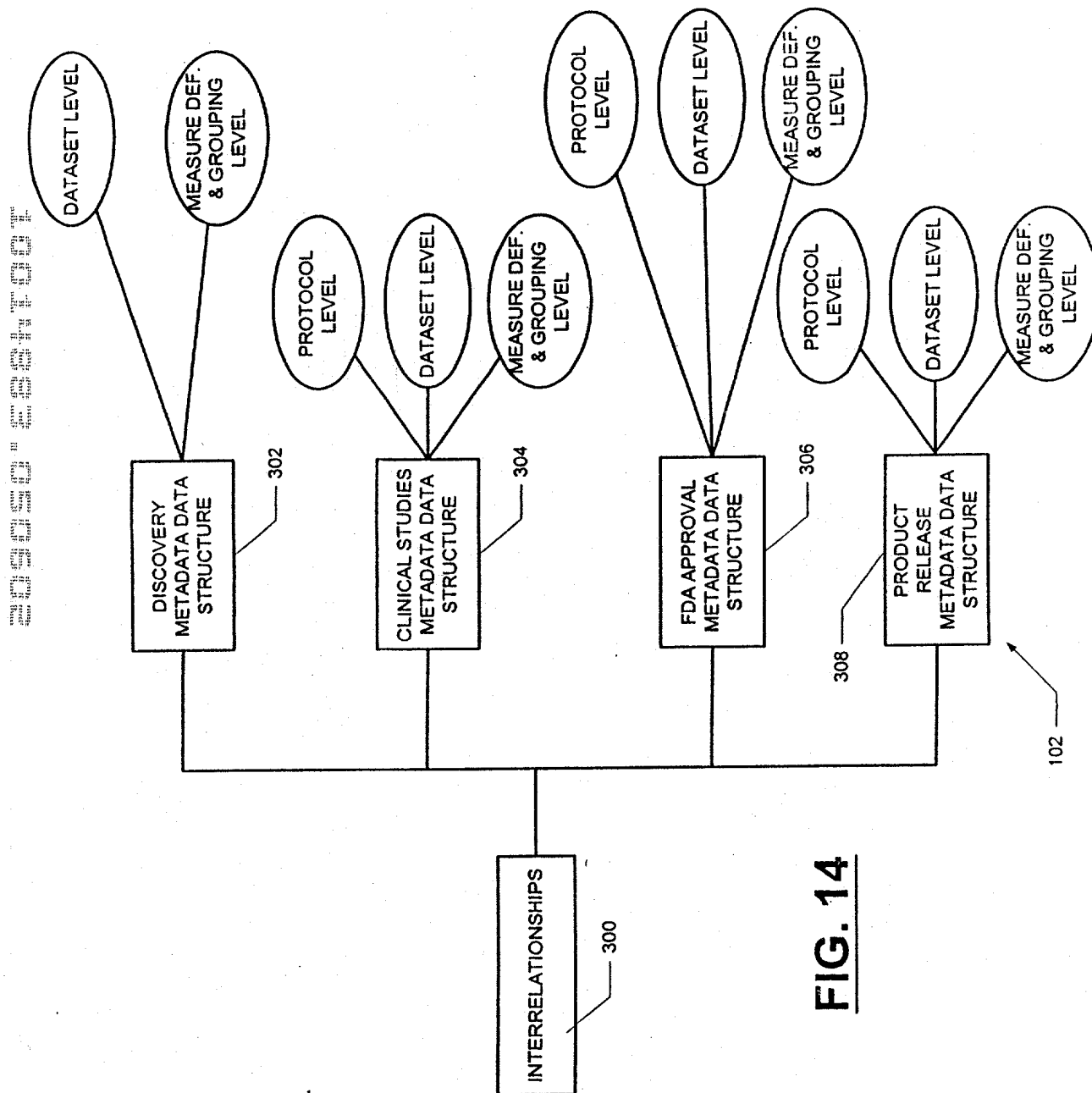


FIG. 14

FIG. 15 is a flowchart illustrating a process for defining and running a process. The process begins with a user request to run a report or data transformation process (320). This leads to a portal (322) where the user defines prerequisite process components, including input and output tables and code segments (322). The user then adds or edits the process (326). The process is then displayed as a hierarchy of pre-defined processes (324). The user can then edit the code (334) or select input data table(s) (330). The user then selects a code segment and defines any process-specific code parameters (332). The user then selects process output (report or data table) (336). The user specifies run-time parameters (340). The process is then run (338), resulting in a report output (342) and an output data table derived by process (344).

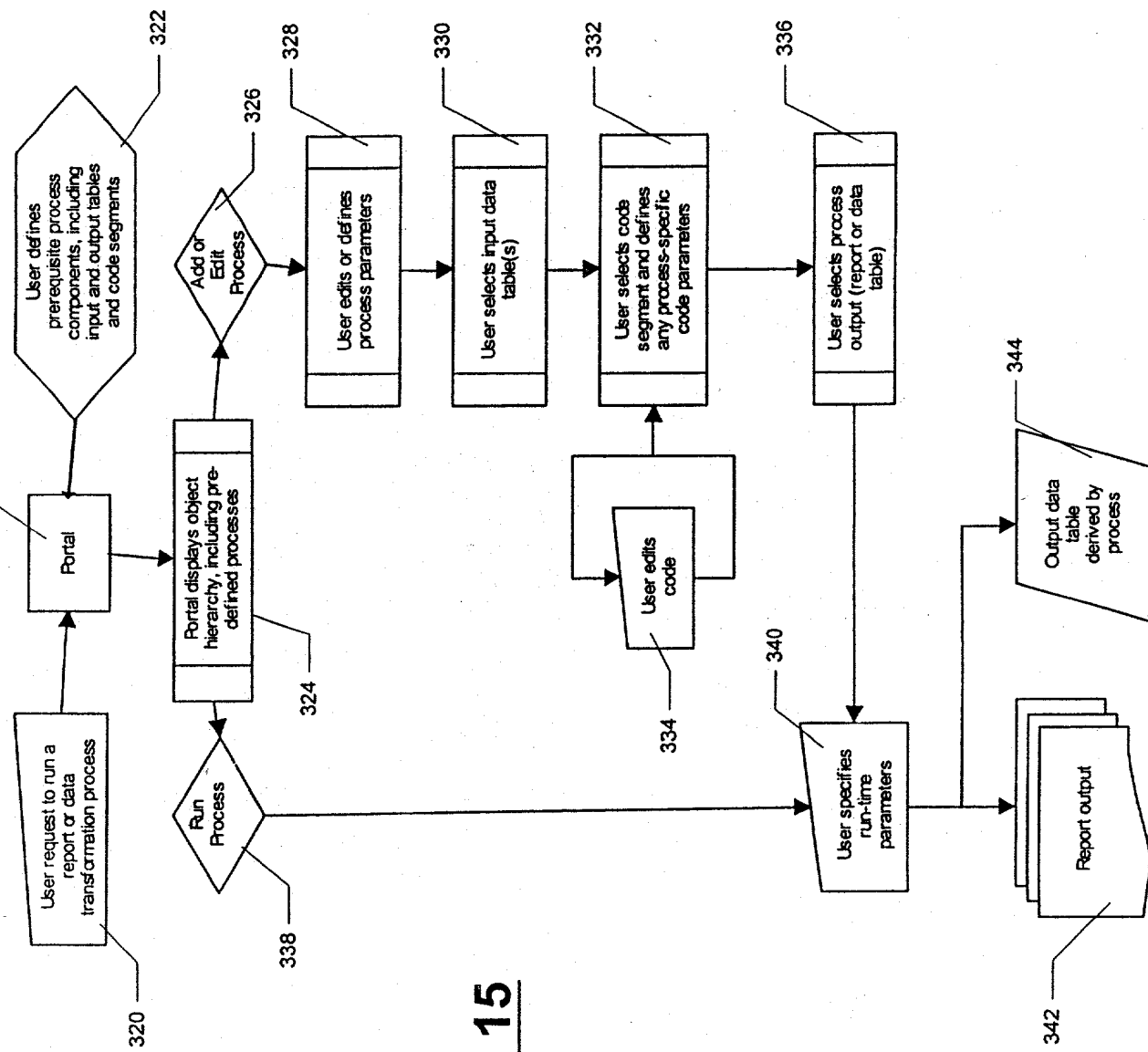


FIG. 15

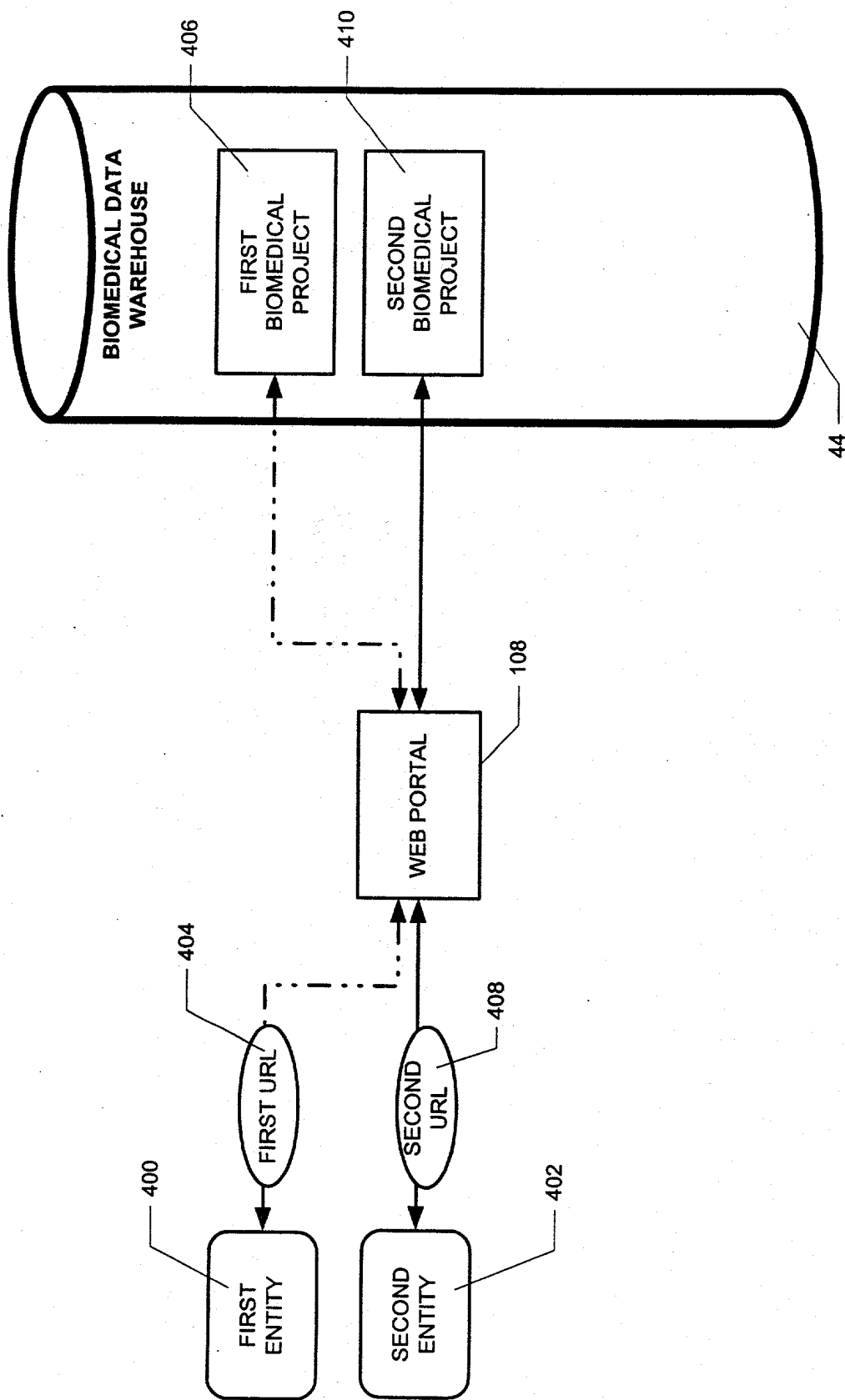


FIG. 16

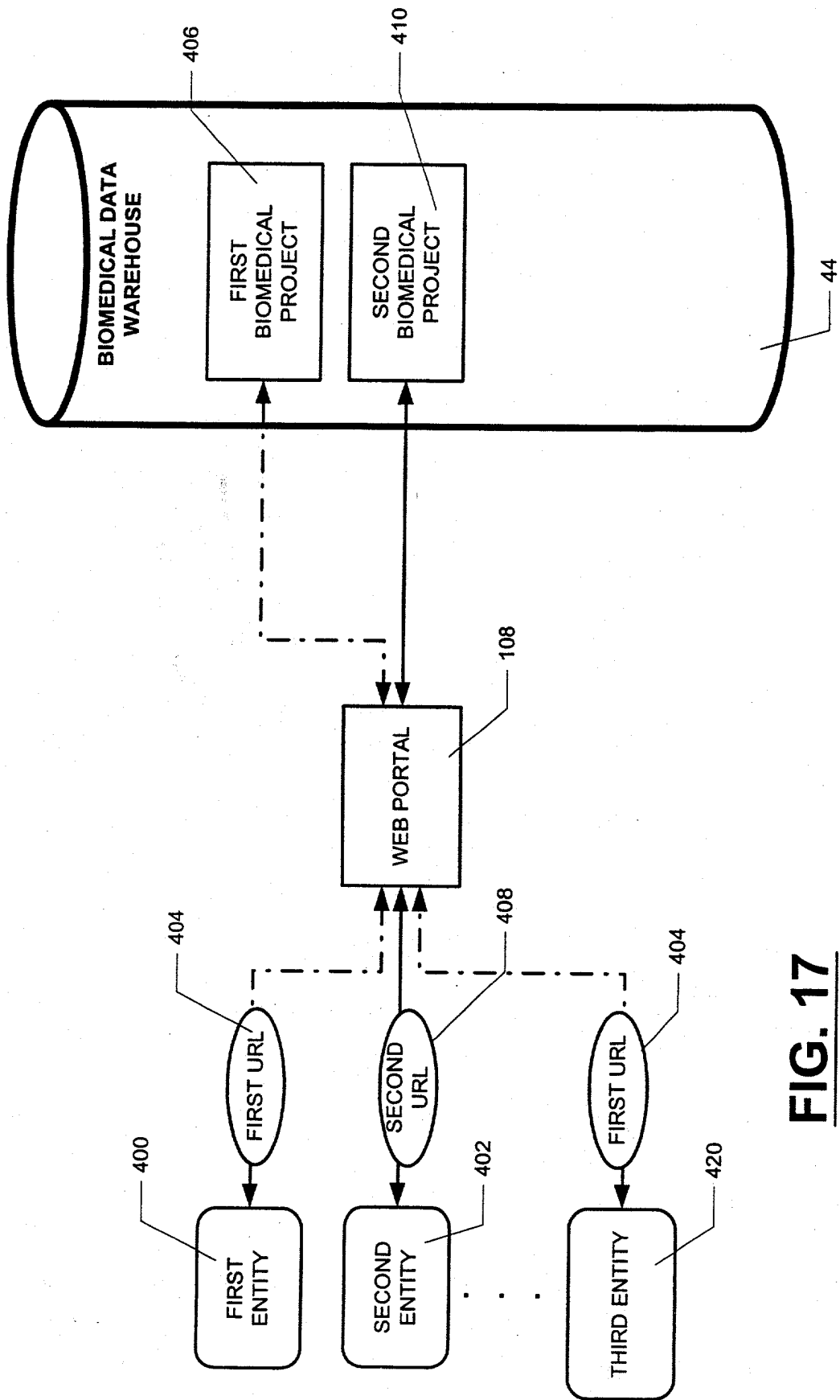
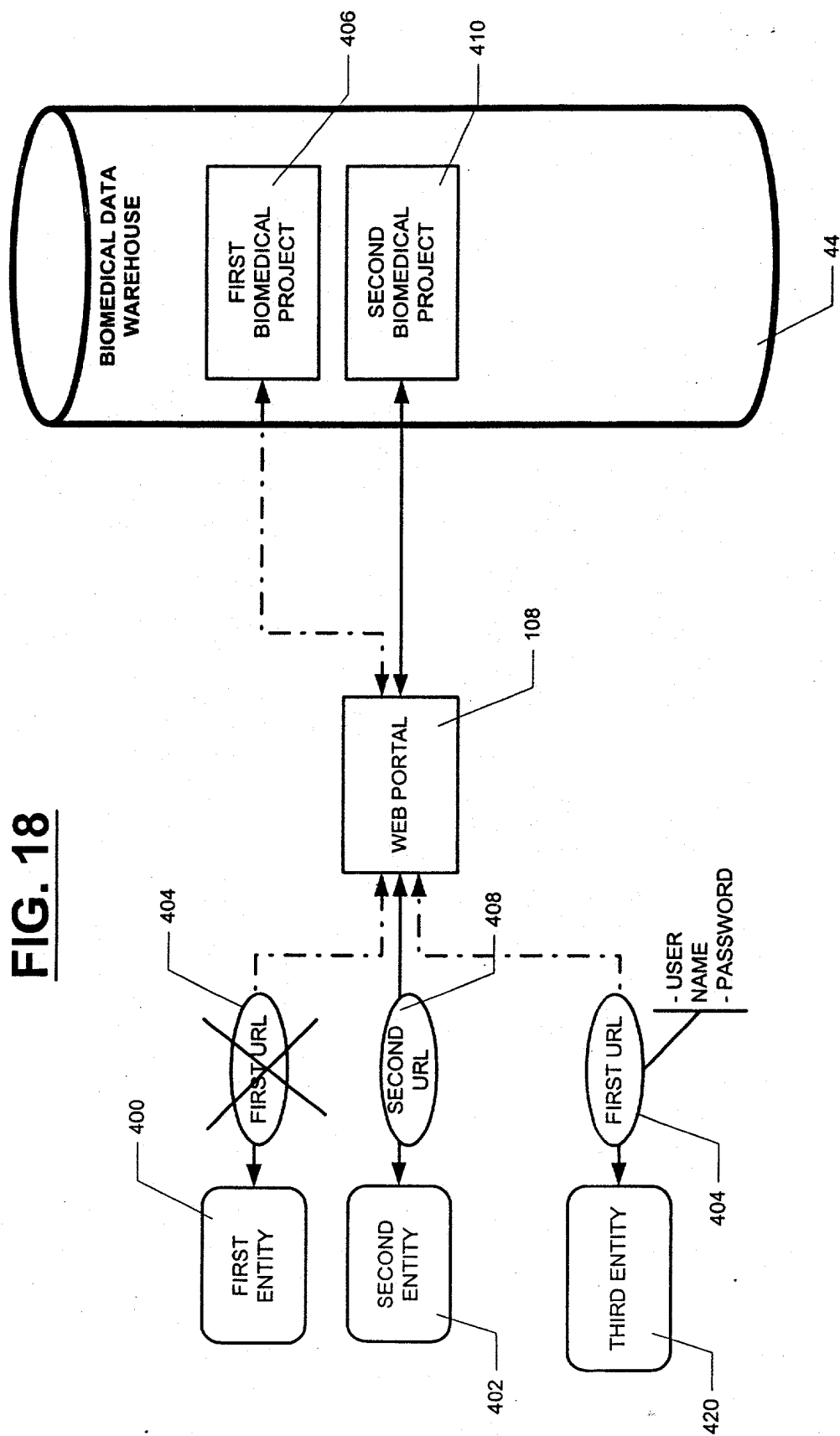
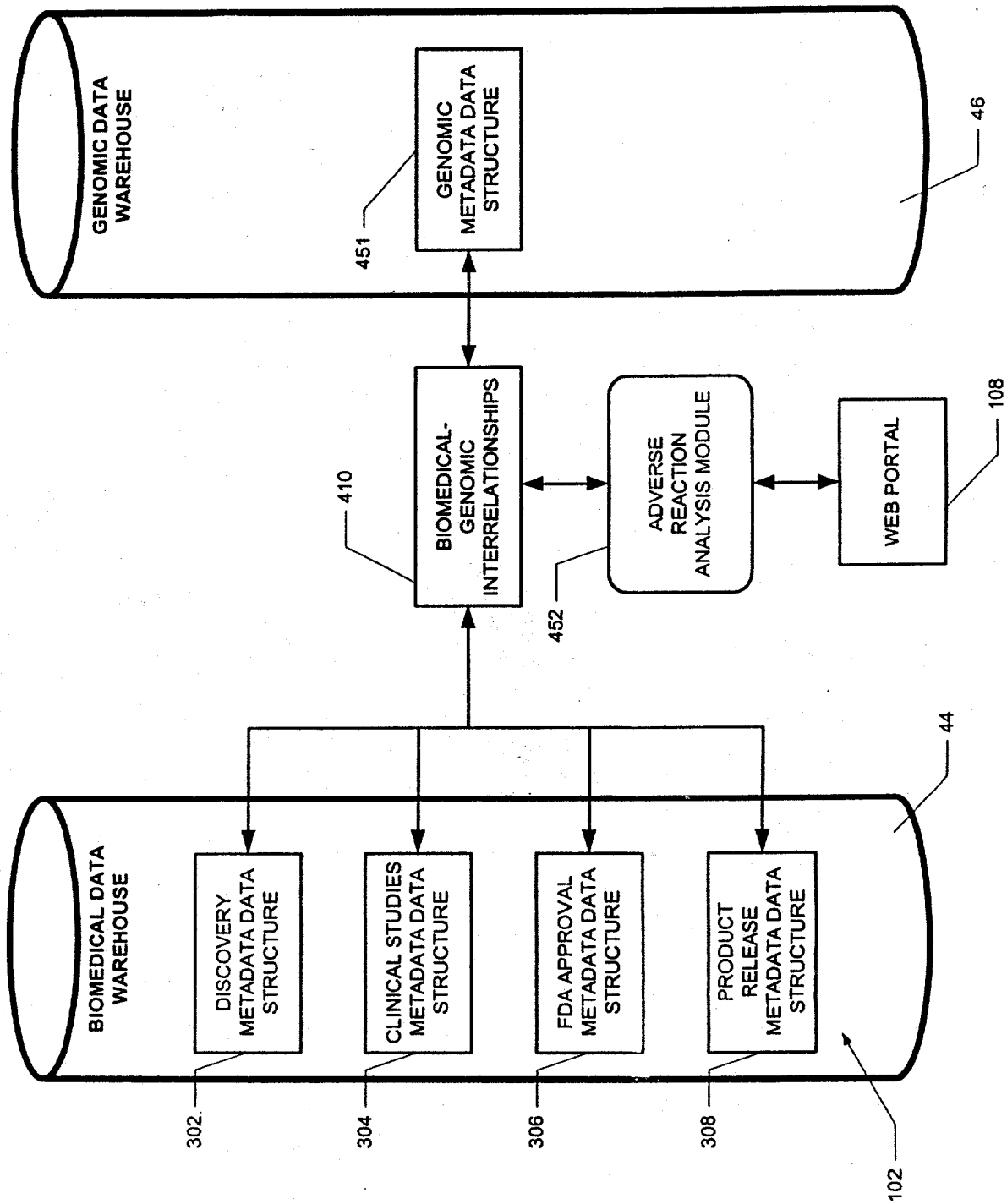


FIG. 17

FIG. 18





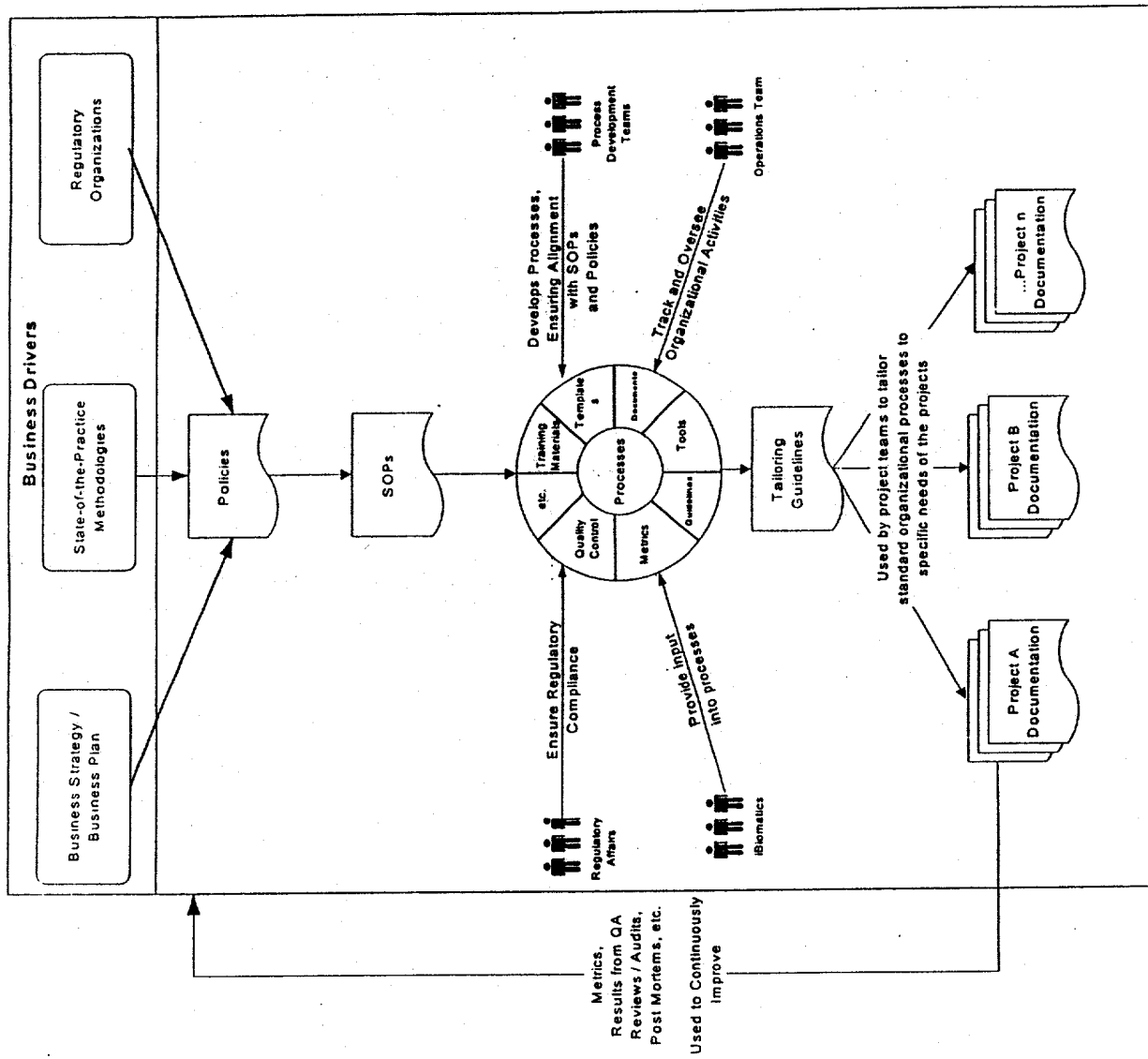


FIG. 20